K103394

# Premarket Notification 510(k) Summary
## Barcode Conical Collimator Verification (BCCV)

JAN 12 2011

The following information is provided following the format of 21 CFR 807.92.

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| **Submitter's Name:** | Varian Medical Systems, Inc.<br>3100 Hansen Way e-110<br>Palo Alto, CA 94304<br><br>Contact Name: Vy Tran<br>Phone: 650/424.5731<br>Fax: 650/842.5040<br>Date: 15 November 2010 |
| **Proprietary Name:** | Barcode Conical Collimator Verification (BCCV) |
| **Classification Name:** | Medical charged-particle radiation therapy system<br>21 CFR 892.5050, Class II<br>Product Code: IYE |
| **Common/Usual Name:** | Barcode Conical Collimator Verification (BCCV) |
| **Predicate Devices:** | 4D Integrated Treatment Console with PAVS, K081036 |
| **Device Description:** | The Barcode Conical Collimator Verification (BCCV) device provides verification of conical collimators for the Varian High Energy Clinac (K100890) and TrueBeam (K092871) devices. Conical collimators are used during stereotactic radiodurgery (SRS) treatments to deliver small diameter treatment beams. The BCCV will prevent treatment until the conical collimator, as required by the treatment plan, has been scanned. |
| **Statement of Indications for Use:** | The Barcode Conical Collimator Verification device assists operators of radiation therapy devices by preventing irradiation until the conical collimator required by the treatment plan is in place. |
| **Technological Characteristics:** | Refer to the Substantial Equivalence Comparison Chart in this dossier. |

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Vy Tran
Official Correspondent
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

JAN 12 2011

Re: K103394
Trade/Device Name: Barcode Conical Collimator Verification (BCCV)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: November 17, 2010
Received: November 19, 2010

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use Form

JAN 12 2011

510(k) Number (if known): K103394

Device Name: Barcode Conical Collimator Verification (BCCV)

Indications for Use:

The Barcode Conical Collimator Verification device assists operators of radiation therapy devices by preventing irradiation until the conical collimator required by the treatment plan is in place.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103394